UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UPMC, a not for profit corporation,
200 Lothrop Street
Pittsburgh, PA 15213

Plaintiff,

–v–

ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201,

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, SW
Washington, DC 20201,

Defendants.

Case No. 2:20-cv-1276

COMPLAINT

Plaintiff UPMC (University of Pittsburgh Medical Center), brings this action on behalf of its wholly owned subsidiaries, UPMC Mercy, UPMC Magee Womens Hospital, UPMC Hamot, UPMC McKeesport, UPMC Horizon, and UPMC Children's Hospital of Pittsburgh ("Subsidiaries"), against Defendants Department of Health and Human Services ("HHS") and Alex M. Azar II, in his official capacity as the Secretary of HHS, and alleges the following:

NATURE OF ACTION

1. Plaintiff brings this action under the Social Security Act and the Administrative Procedure Act ("APA") to challenge certain provisions of final rules issued on November 13, 2017, November 21, 2018, November 12, 2019 by the Centers for Medicare and Medicaid

Services ("CMS"), an agency within the Defendant HHS. *See* 82 Fed. Reg. 52,356, 52,493-52,511, 52,622-52,625 (Nov. 13, 2017); 83 Fed. Reg. 58,818, 58,981 (Nov. 21, 2018); 84 Fed. Reg. 61, 142, 61,321–24 (Nov. 12, 2019). The rules concern the Hospital Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs for Calendar Years 2018, 2019 and 2020. The portions of the rules being challenged in this case reduced by nearly 30% Medicare reimbursements to certain public and not-for-profit hospitals and clinics for prescription drugs purchased by those institutions on a discounted basis under section 340B of the Public Health Service Act (the "340B Program"). These challenged portions of the rules will hereafter be referred to as the "340B Provisions of the OPPS Rules" or "the OPPS Rules."

2. Congress enacted the 340B Program in 1992 and through that Program lowered the cost of drugs purchased by certain public and not-for-profit hospitals and federally funded clinics serving large numbers of low-income patients. By lowering hospitals' purchase costs for patient drugs, Congress enabled these hospitals to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. REP. No. 102–384(II), at 12 (1992). *See also* 82 Fed. Reg. at 52,493 & n.18 (quoting House report and noting that "[t]he statutory intent of the 340B Program is to maximize scarce Federal resources as much as possible, reaching more eligible patients").

3. The 340B Provisions of the new OPPS Rules specially target the Medicare portion of this benefit of the Program for 340B hospitals that serve the poor. The OPPS Rules eliminate nearly all of the differential between national Medicare reimbursement rates and the discounted purchase costs mandated for 340B hospitals, costing those hospitals an estimated (by CMS) $1.6 billion, in violation of both the Secretary's statutory authority under the Social

Security Act to reimburse hospitals for outpatient drugs and the purpose and design of the Public Health Service Act provisions establishing the 340B program.

4. Plaintiff UPMC's Subsidiaries have used the 340B Program to provide critical healthcare services to their communities, including to underserved patient populations in those communities. UPMC and its Subsidiaries and the populations they serve, have suffered significant harm from the negation of the cost-reimbursement differential through the 340B Provisions of the OPPS Rules. Plaintiff is entitled to declaratory and injunctive relief from this Court setting aside the 340B Provisions of the OPPS Rules.

PARTIES

5. Plaintiff UPMC is a world-renowned nonprofit health care provider that provides more than $1.4 billion a year in benefits to its communities, including more care to the region's most vulnerable citizens than any other health care institution. UPMC Mercy, UPMC Magee Womens Hospital, UPMC Hamot, UPMC McKeesport, UPMC Horizon, and UPMC Children's Hospital of Pittsburgh are all wholly owned UPMC subsidiary hospitals. UPMC's Subsidiaries participate in the 340B Program and rely heavily on the price differential created by Congress through that Program to generate resources that are used to provide critical health care programs for the communities they serve, including vulnerable populations within those communities. UPMC and the UPMC Subsidiaries have been significantly harmed by the elimination of this differential from Medicare payments in the OPPS Rules and will continue to be significantly harmed if the OPPS Rules remains in effect.

6. Defendant HHS is a cabinet-level department of the United States government headquartered at 200 Independence Avenue, SW, Washington, D.C. 20201. CMS, which issued the 340B Provisions of the OPPS Rules, is an agency within HHS.

7. Defendant Alex M. Azar II ("the Secretary") is the Secretary of Health and Human Services") and maintains offices at 200 Independence Avenue, SW, Washington, D.C. 20201. In that capacity, he is responsible for the conduct and policies of HHS, including the conduct and policies of CMS. Secretary Azar is sued in his official capacity.

JURISDICTION AND VENUE

8. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*., section 340B of the Public Health Services Act, 42 U.S.C. § 256b, and the Administrative Procedure Act, 5 U.S.C. § 701–06.

9. This Court has subject matter jurisdiction over this action under 42 U.S.C. § 405 and 28 U.S.C. § 1331.

10. This judicial district is an appropriate venue pursuant to 28 U.S.C. § 1391(e), 42 U.S.C. § 405(g), and 42 U.S.C. § 1395ff(b)(2)(C)(iii).

STATUTORY AND REGULATORY BACKGROUND

A. The 340B Program

11. Congress established the 340B Program in 1992 as part of the Public Health Service Act. The 340B Program provides certain hospitals serving a disproportionate share of low-income individuals and federally funded clinics (called "covered entities" in the statute) with outpatient prescription drug discounts comparable to those that Congress had made available to state Medicaid agencies in 1990. Under the 340B Program, private prescription drug manufacturers, as a condition of having their outpatient drugs be reimbursable through state Medicaid programs, are required to offer covered entities discounts calculated pursuant to a statutory formula. 42 U.S.C. § 256b(a)(1). As the Health Resources & Services Administration ("HRSA"), the agency within HHS responsible for administering the 340B Program, has

recognized, the purpose of the Program is to enable eligible public and not-for-profit hospitals and other covered institutions to use their scarce resources to reach more patients, and to provide more comprehensive services.

12. Since the 340B Program was first implemented, covered entities have retained the savings generated through the program and have used them to provide additional critical healthcare services for their communities, including underserved populations within those communities − for example, by increasing service locations, developing patient education programs, and providing translation and transportation services.

13. Recognizing the value of the 340B Program, Congress has increased the categories of eligible "covered entities." In 1992, when Congress first created the Program, "covered entities" included federally funded health centers and clinics providing services such as family planning, AIDS intervention, and hemophilia treatment, as well as public and certain not-for-profit hospitals serving a large proportion of low-income populations. *See* 42 U.S.C. §§ 256b(a)(4)(A)-(E), (G), (L). In 2010, as a part of the Affordable Care Act, Congress expanded "covered entities" to include certain children's hospitals, free-standing cancer hospitals, critical access hospitals, and sole community hospitals. *See* 42 U.S.C. § 256b(a)(4)(M)-(O).

14. Plaintiff's Subsidiaries are "covered entities" under the 340B Program and are paid under the OPPS system.

B. Medicare OPPS Reimbursement

15. In 1997, Congress acted to control Medicare expenditures for outpatient services and directed CMS to develop a hospital Outpatient Prospective Payment System ("OPPS") for

Medicare to pay for services offered by hospitals' outpatient departments, for example rehabilitation services. *See* 42 U.S.C. § 1395*l*. CMS updates the OPPS payment rates annually.

16. Beginning in 2004, Congress required CMS to set reimbursement rates for separately payable drugs, *i.e.*, covered outpatient drugs that are not bundled into the price of an outpatient service. These drugs include outpatient drugs covered under the 340B program.

17. A provision of the statute provides CMS with two choices in setting Medicare reimbursement rates for separately payable drugs in 2006 and subsequent years. Under Subclause I of that statutory provision, CMS must set rates based on the acquisition costs of these drugs, if specified statistically sound survey data on acquisition cost are available for each drug. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). Under Subclause II, if the specified acquisition cost data are not available, CMS is required to reimburse based on average sales price ("ASP")—a defined quantity under a different statutory provision—plus 6%. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II).

18. In 2012, after concluding that it could not obtain the acquisition cost required in order to reimburse under Subclause I based on acquisition cost, CMS adopted the reimbursement method under Subclause I -- the statutory default rate of ASP plus 6% -- for all separately payable drugs. CMS applied this statutory default rate without further adjustments for each subsequent year, until January 1, 2018.

C. CMS's OPPS Rules Reducing Payment Rate for 340B Drugs

19. On July 13, 2017, CMS issued its proposed rule on OPPS and Ambulatory Surgical Center payment systems for the Calendar Year 2018. In addition to updating the OPPS with 2018 rates, CMS proposed to change how Medicare pays certain hospitals for separately payable drugs purchased under the 340B Program. 82 Fed. Reg. 33,558, 33,634 (July 20, 2017).

Specifically, CMS proposed lowering the government payment rate for such drugs from the previous (statutory default) rate of ASP plus 6% to ASP minus 22.5% -- a reduction in the reimbursement rate of 28.5 %. *Id.* at 33,634.

20. CMS admitted that its reason for proposing this reduction was that a lower reimbursement rate would better reflect the acquisition cost of the drugs. According to CMS, the new rate would better recognize "the significantly lower acquisition costs of such drugs incurred by a 340B hospital," *id.*, and "better represent[] the average acquisition cost for these drugs and biologicals," *id.* at 33634. On November 1, 2017, CMS issued the final version of the 340B Provisions of the OPPS rule, adopting the proposed rate of ASP minus 22.5% for drugs purchased under the 340B Program. 82 Fed. Reg. 52,356, 52,362.

21. CMS adopted the same rate of ASP minus 22.5% for drugs purchased under the 340B Program in its 2019 and 2020 OPPS rules. 83 Fed. Reg. 58,818, 58,981 (Nov. 21, 2018); 84 Fed. Reg. 61, 142, 61,321–24 (Nov. 12, 2019).

22. This new reimbursement rate nearly eliminated the benefit of the 340B program for certain covered entities for Medicare/340B drugs by eliminating the difference between the purchase price paid *by* hospitals for those drugs and Medicare payments *to* hospitals for those drugs.

23. In reducing the payment rate for certain 340B drugs by nearly 30%, CMS purported to rely on its authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), which allows the Secretary to "calculate" and "adjust" the statutory default rate of ASP plus 6%. *E.g.*, 82 Fed. Reg. at 52,499 (noting that "calculate and adjust" authority gives the Secretary "broad discretion" to adjust payments for drugs). The 340B Provisions of the OPPS Rule exceed the Secretary's authority because the reduction set forth in the Rule is expressly based on the

estimated acquisition costs of 340B drugs, *i.e.*, a variation of the cost-based methodology set forth under Subclause I of the applicable statutory provision, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). *E.g.*, 82 Fed. Reg. at 52,501. Because CMS, by its own admission, cannot now and has never been able to reliably collect the statistically significant cost data for each drug required under the statute to invoke Subclause I, it improperly sought to use *aggregate* acquisition costs as estimated by the Medicare Payment Advisory Commission ("MedPAC") as a proxy for that data in issuing the OPPS Rule – even though payment under Subclause II expressly must be based on average sales price, *not* acquisition costs. In doing so, the Secretary impermissibly invoked his authority under Subclause II to circumvent the requirements under Subclause I.

24. The Secretary's authority under Subclause II of the applicable statutory provision, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), to "calculate" and "adjust" the ASP-plus-6% formula, does not allow CMS to reduce the statutory rate by nearly 30%, depriving affected hospitals of drug-price savings totaling an estimated $1.6 billion (CMS's estimate). Rather, this authority only permits the Secretary to calculate the ASP as set forth in the statute and to fine-tune the default rate.

25. The 340B Provisions of the OPPS Rules also exceed the Secretary's authority because they undermine the 340B Program by depriving eligible hospitals of a critical portion of the resources Congress intended to provide those hospitals through 340B discounts. CMS's efforts in the 340B Provisions of the OPPS Rule to "align" (82 Fed. Reg. at 52,495) the purchase price of 340B drugs with reimbursements for those drugs is directly contrary to Congress' intent to create a differential between reimbursements and purchase prices and thereby to generate resources for covered entities to use in their communities.

26. The new payment rate set forth in the 340B Provisions of the OPPS Rules has substantially impacted the day-to-day operations of UPMC and its Subsidiaries which rely on the 340B savings, and the price differential Congress created through that program, to provide vital health services to their communities, including vulnerable and underserved populations within those communities. Elimination of the differential in connection with Medicare payments for 340B drugs will threaten the poor and underserved populations who depend on 340B hospitals, in direct contravention of the purpose and design of the 340B program.

ADMINISTRATIVE REVIEW OF PLAINTIFF'S CLAIMS FOR PAYMENT

27. After a health-care provider performs Medicare-eligible services, it submits a claim for reimbursement to a Medicare Administrative Contractor ("MAC"). The MAC makes an initial determination whether to pay the claim, and if so, how much to pay. 42 C.F.R. § 405.920. If the MAC denies a claim for payment in whole or in part, the Social Security Act provides a four-level administrative appeal process. First, the provider may present its claim again to the MAC for "redetermination." 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. Second, the provider may seek "reconsideration" from a Qualified Independent Contractor ("QIC"). 42 U.S.C. § 1395ff(c); 42 C.F.R. § 405.960. Third, the provider may seek *de novo* review by an administrative law judge in the Office of Medicare Hearings and Appeals. 42 U.S.C. § 1395ff(d)(1); 42 C.F.R. §405.1000–58. Fourth, the provider may seek *de novo* review by the Medicare Appeals Council, which is a part of the HHS Departmental Appeals Board. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 1100.

28. If HHS's final decision after this process is unfavorable, a provider may seek judicial review. 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.1136.

29. Between February 12, 2018 and July 2, 2019, Plaintiff, through its Subsidiaries presented claims for payment to Novitas, a MAC, for separately payable drugs subject to the 340B Program. All of those claims were paid at approximately 30% less than what had been paid in 2017.

30. Plaintiff submitted redetermination requests to Novitas for all of those claims in which it demanded full reimbursement of ASP plus 6%. Novitas issued unfavorable decisions on each of the redetermination requests.

31. Plaintiff submitted reconsideration requests regarding its claims to C2C, the QIC with jurisdiction over the claims submitted to Novitas. C2C upheld the Novitas decisions.

32. Plaintiff submitted requests to the Office of Medicare Hearings and Appeals for review by an Administrative Law Judge ("ALJ") of C2C's decisions on each of Plaintiff's reconsideration requests. The ALJ dismissed Plaintiff's requests.

33. Plaintiff then submitted requests for review to the Medicare Appeals Council of the Departmental Appeals Board. The requests for review were dismissed. *See* Exhibits A & B.

34. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), Plaintiff has a right to judicial review of the Council's order. Plaintiff's claims, which total approximately $1.5M, meet the minimum threshold for the amount in controversy. *See* 84 Fed. Reg. 53,444, 53,445 (Oct. 7, 2019).

COUNT 1

OPPS RULE – VIOLATION OF THE SOCIAL SECURITY ACT

35. Plaintiff incorporates by reference the foregoing paragraphs.

36. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

37. The nearly 30% reduction in payment for 340B drugs under the OPPS Rule is arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT 2

UPMC CLAIMS – VIOLATION OF THE SOCIAL SECURITY ACT

38. Plaintiff incorporates by reference paragraphs 1 through 34.

39. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

40. The remittances to UPMC for the claims that are the subject of this lawsuit reflected a nearly 30% reduction in payment that was arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court issue judgment in its favor and against Defendants:

A. Declaring that the 340B Provisions of the 2018, 2019, and 2020 OPPS Rules are an unlawful exercise of Defendants' authority, in violation of the Social Security Act and section 340B of the Public Health Service Act;

B. Directing Defendants to reimburse UPMC and its Subsidiaries the difference between what they were paid for the claims that are the subject of this lawsuit and what they should have been paid for those same drugs under the statutory methodology of ASP plus 6%.

C. Directing Defendants to conform the payment methodology that they use for 340B drugs in 2020 and subsequent years to the requirements of the Social Security Act, and specifically not to use acquisition costs to calculate prices unless Defendants have complied with 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I); and

D. Granting such other relief to which Plaintiff may be entitled at law or in equity.

Dated: August 28, 2020

Respectfully submitted,

/s/ John A. Schwab

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